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(54) **Prosthesis for knee replacement**

Knieprothese

Prothèse de genou

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**EP-A- 0 349 173 EP-A- 0 442 330
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EP 0 626 156 B1

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Description

This invention relates to prostheses for knee replacement.

Background of the Invention

Most of the knee replacement designs in current use are of the Condylar Replacement type, where the arthritic joint surfaces are resected and are replaced with metal and plastic surfaces. There are two conflicting requirements in design; first, the desirability for freedom of motion requires relatively low conformity between the femoral and tibial surfaces, while the desirability for low contact stresses on the plastic surface requires high conformity. This conflict similarly applies to the patello-femoral bearing joint.

US-A-4224696 discloses a tibial base plate for a knee prosthesis which comprises a metal platform which has an upwardly concave surface and a plastics meniscal component which has a convex undersurface.

Summary of the Invention

According to the invention there is provided a tibial component of a knee prosthesis which comprises an upwardly concave metal platform adapted to be secured to a resected tibia and a plastics bearing component mounted for sliding movement thereon, the mating surface between the plastics component and the metal platform being substantially cylindrical with the axis of the cylinder extending in a lateral-medial line.

By providing for sliding movement in the anterior-posterior direction, the prosthesis has freedom of movement in the anterior-posterior direction, which allows a higher degree of flexion, while reducing shear stresses in the component-bone interfaces.

The cylindrical bearing surface between the plastics component and the metal platform viewed in a sagittal plane constrains the movement in the anterior-posterior direction. Also, the upwardly curved interface between the plastics component and the metal platform introduces increasing constraint due to gravity forces as the plastics bearing component displaces further away from its central position.

Various features and advantages of the present invention will become clear from the following description and accompanying drawings in which:-

Figures 1(a), (b), (c), (d) and (e) are perspective views of the normal knee at various degrees of flexion from 0 to 120°.

Figure 2(a) is a perspective view of a knee fitted with a prosthesis in accordance with the invention at zero flexion,

Figure 2(b) is a perspective view of the knee (with the femur removed for clarity), fitted with same prosthesis at approximately 90° flexion,

Figure 3(a) is a perspective view of a femoral com-

ponent in accordance with a first embodiment of the invention,

Figure 3(b) is a view similar to Figure 3(a) of a modified form of the femoral component,

Figure 3(c) is a perspective view of a tibial component intended for use with the femoral component of Figure 3(b),

Figure 4(a) is a perspective view similar to Figure 3(a) of a further embodiment in accordance with the invention and Figure 4(b) shows a perspective view of a corresponding tibial component,

Figures 5(a), (b) & (c) show, diagrammatically, sagittal views of a prosthesis in accordance with the invention (Figures 5(b) & (c)) compared with a conventional design (Figure 5(a)),

Figure 5(d) is a sagittal view of the profile of a patella replacement (in broken lines) compared with a conventional replacement (full lines),

Figure 6 is an underside view of a femoral component showing the conformity of the patella with the patella groove,

Figure 7(a) is a plan view of a tibial component in accordance with the invention,

Figure 7(b) is a section taken on the line B-B in Figure 7(a),

Figure 7(c) is a section taken on the line A-A in Figure 7(a),

Figure 8(a) is a plan view of a modified tibial component,

Figure 8(b) is a section taken on the line A-A in Figure 8(a) but with the anchoring pegs omitted,

Figure 9(a) is a plan view of a further embodiment of tibial component and Figure 9(b) is a view taken on the line A-A in Figure 9(a), and

Figure 10 is a view similar to Figures 7(b), 8(b) and 9(b) of a modified tibial component showing alternative ways of guiding the plastics component.

Figure 1 of the accompanying drawings shows a sagittal view of the natural knee at different flexion angles - 0 to 120° in thirty degree steps. The distal end 1 of the femur 2 can be seen to have a larger radius than the posterior 3. At zero degrees flexion, the larger radius distal end 1 contacts the top of the tibia 4, resulting in greater conformity and a greater area of contact. Other structures increase the contact area, notably the menisci; which are deformable discs interposed between the femoral and tibial condyles. When the knee is flexed, the femoral-tibial conformity is reduced, which would reduce the contact area and result in high contact stresses. However, the deformable menisci take up the shape between the femoral and tibial surface and once again spread the load. If the menisci are removed for injury, in later years, there is an increased chance of osteoarthritis.

The knee displays both laxity (which can be termed freedom of motion) and stability, which is the control of displacements and rotations to within acceptable limits. Laxity can include linear or rotational translation in any

of the three mutually perpendicular coordinate axes. For purposes of the invention, laxity is only considered in anterior-posterior displacement, medial-lateral displacement and internal-external rotation, these being the most significant. The anterior-posterior stability is provided mainly by the cruciate ligaments. The anterior cruciate 5 can be seen in Figure 1, especially at the higher flexion angles. Rotational stability is provided by a combination of the cruciate and collateral ligaments. The muscles also play an important role in providing stability. The joint surfaces contribute to stability as force is applied across the joint, due to the slight dishing of the surfaces and the deformability of the articular cartilage. The laxity is due to the elastic extensibility of the ligaments, the joint surfaces, and other soft tissues surrounding the joint.

The patella is an important bone which transmits the force between the quadriceps and the upper tibia. In broad terms it can be regarded as a pulley, sliding up and down on the front of the femur. The patella fits closely into a groove on the front of the femur, such that the contact areas are broad bands across the width of the patella. Beyond about 90 degrees of flexion, the contact splits into two parts as the patella straddles the intercondylar groove.

When a condylar replacement is introduced (Figure 2), a femoral component 20 is attached to the end of the femur and a tibial component 21 to the upper part of the tibia. Normally, the ends of the femoral condyles are resected and shaped to receive the femoral component and held in place with bone cement and/or pegs extending into the condyles. The collateral and cruciate ligaments can be preserved by providing a slot 22 in the femoral component, although in most designs, either the anterior is resected, or both cruciates are resected. The patella 23, either the natural patella or a replacement, fits into the groove 24. When the knee is flexed with conventional prostheses, there is now a distinct lack of conformity between the femoral and tibial surfaces, with the result that the contact stresses on the plastic surface are high, leading to failure due to breakdown of the plastic in many cases.

Prior designs suffer from a number of problems; for example there is no meniscus to spread the force as in the normal knee. If the anterior cruciate is resected, there should ideally be a posterior upsweep of the tibial plastic surface to compensate, and if the posterior cruciate is resected also, an anterior upsweep is needed. In angles of flexion beyond about 90 degrees, there are two separate contacts on the patella component, leading to high stresses and deformation, and also sometimes 'catching'.

A typical femoral component is shown in Figure 3 (a). The condylar surfaces 31 resemble the anatomical, especially in the sagittal view, and there is a cut-out or slot 32 for one or both cruciate ligaments. A patella groove 33 is continuous down to the cut-out 32 after which it splits. The larger femoral component in Figure 3(b) now has continuous surfaces throughout, including

the patella groove, but is otherwise the same. Such a configuration requires resection of both cruciate ligaments. The femoral shape is then used to computer-generate a tibial surface 35, based on input laxity requirements in anterior-posterior displacement and internal-external rotation. A computerised method of generating tibial surfaces is described in US Patent No. 4822365. The new femoral shape has two advantages. First, the contact on the tibial surface can now be spread over the entire width of the tibial surface, thus increasing the contact area. Second, the patella has a continuous track, and can maintain a broad contact area throughout motion, without a split of the contacts at higher flexion. However, there is still the disadvantage that the radius of curvature of the distal femur is greater than the posterior, such that once flexion is initiated, the smaller femoral radius contacts the tibia giving a reduction in contact area.

Figures 4(a) and 4(b) shows one solution to this problem. Here, the radius of the posterior portion 41 of the femoral component has been carried round to the distal femur 42. Now there is a constant radius R for contacting the tibial surface 43. A surface computer-generated with this component is clearly more dished than the previous component and provides an increase in the contact area throughout. The reduction in the contact stresses are calculated to be significant. Another benefit of the new surfaces is the enhanced stability. In the surfaces of Figure 3, it can be imagined that the flexed femur can slide forwards on the tibia with relatively little resistance. However, in Figure 4, the anterior sliding is much more restricted because of the steeper slope of the anterior tibial surface.

Certain characteristics of this design form are illustrated in Figure 5 which shows sagittal views of a standard design (Figure 5(a)) and a non-standard design, (Figures 5(b) and 5(c)). The differences in the distal femoral radii can be clearly seen. This change in distal radius has three consequences. More resection of anterior bone is needed for installation, although this is not a serious problem. The second problem is that the patella mechanics are altered. An important parameter of patella function is the lever arm, because this helps to determine quadriceps efficiency. With the knee at zero flexion, the lever arms are similar, but in mid-flexion (around 45 degrees), it can be appreciated that the lever arm of the design on the right will be reduced. This may not be a serious problem, but a possible remedy is to treat the bearing surfaces and patella surfaces as separate. The patella surface would then protrude as normal, in between the bearing surfaces. Such a solution reduces the width of the main bearing areas and may not represent an overall advantage. A final characteristic is that the femoral-tibial contact point is more posterior than normal. This has the advantage of improved quadriceps efficiency, as noted, but may result in upwards tilting of the front of the tibial component. If necessary, the position of the bottom of the curvature on the tibial surface could be moved anteriorly by 2-3mm

which would alleviate this problem.

An improvement to the patello-femoral contact is apparent from Figure 5. The normal dome-shape (Figure 5(a)) has high conformity when seen in the overhead view (Figure 6), but low conformity in the sagittal view. Several experimental and theoretical studies have shown that the angle through which the patella rotates relative to the femoral component in the sagittal plane is within 10 degrees (Figure 5(b) and 5(c)). This means that a high degree of conformity can be designed into the patella with no loss in freedom of motion. The new sagittal profile of the patella is shown dotted in Figure 5(d). As can be seen, instead of having a continuous convex shape in sagittal view, it has a flattened inner face 51 and outwardly extending surfaces 52 (Figure 6), giving greater conformity with the sides of the patella groove 53. Such increase in conformity leads to greatly reduced contact stresses. A consequence of such a design is that if surgical placement is rotationally incorrect, there would be restriction of motion. However, the curvatures can be adjusted to allow for an appropriate margin of error.

The above design form is most suitable when the anterior and posterior cruciate ligaments are resected. In this case, there will still be sufficient anterior-posterior laxity (approximately 5 mm total) and rotational laxity (+ - 12 degrees), without restriction from taut ligaments. Such laxity will also be sufficient for activities of everyday living. The disadvantage is that the components are relied upon for stability, and in the long run, this may lead to problems with the fixation of the components to the bone. In addition, resection of the cruciates is believed to reduce the proprioceptive response of the knee with consequent compensatory gait patterns. A further disadvantage is that extremes of motion which occur during more demanding activities may be restricted, a possible disadvantage to younger or active patients. One approach to this problem is to use a meniscal bearing type of arrangement, already embodied in several designs, notably the LCS New Jersey, the Oxford, the Minns, and the Polyzoides - see US Patents Nos. 4340978 and 4085466. In these designs, anterior-posterior translation and internal-external rotation is completely unrestricted, except by impingement of the plastic bearing pieces onto capsular soft tissue at the anterior and posterior of the tracks. An important restriction to the designs however is that both the anterior and posterior cruciate ligaments are required, otherwise the stability is insufficient and the plastic bearings can dislocate.

At least two of the designers of the above-named devices have considered the distal-posterior radius problem of the femoral component. If the radii were different, as in Figure 3, then the main advantage of the meniscal bearing concept, complete contact and low stresses, would be lost. US Patent No. 4,340,978 shows the meniscal bearing concept. In Figures 1 and 3 of this US Patent, the Oxford scheme is shown in US Patent No. 4,085,466. A uni-condylar femoral component has a

spherical radius, but does not carry up into a patella flange. The New Jersey design opts for smaller radii posteriorly than distally (Figure 22), and illustrates the loss of full conformity in flexion in Figure 33.

One further improvement provided by the present invention is to provide for sufficient anterior-posterior and rotational stability so that the prosthesis can be used with or without the cruciate ligaments, and to provide complete femoral-tibial conformity throughout the entire range of flexion. In essence, it consists of making the polished metal platform for supporting the plastic bearing piece or pieces concave when seen in the sagittal view. The effect will be to offer steadily increasing resistance to displacement away from the neutral position. In this respect, the stability and laxity characteristics can be made similar to that of a normal knee, or to a usual type of condylar prosthesis. The schematic views (Figure 7(a)) shows the overall arrangement seen in plan view, with a metal plate or platform 71, for attachment to the tibia, having a polished cylindrical surface on the top of the plate and a plastic bearing component 72 which slides on the polished surface. The femoral condylar surfaces are intended to have a constant sagittal radius in the region which articulates against the plastic surface, and conform closely with the tibial surface in both frontal and sagittal planes. An important feature is that the radius of the plastic surface is smaller than that of the cylindrical surface. The cylindrical shape of the bearing surfaces is shown in Figure 7(b) in which R^2 is greater than R^1 . Figure 7(c) shows the medial-lateral section and a central fixation peg 73 and anti-rotation pegs 74 to prevent the platform 71 rotating on the tibia.

For a one-piece plastic component of the kind shown in Figures 7(a) - 7(c), rotation is not possible without loss of complete contact on the cylindrical surfaces. However, anterior-posterior displacement is possible. The arrangement providing anterior-posterior motion from a one-piece plastics [tibia] bearing component is shown in Figures 8(a) and 8(b). The metal platform 81 supports a plastics bearing component 82 which is guided for anterior-posterior motion on a rail 83 fixed or integral with the platform 81. The platform is curved in the sagittal plane as shown in Figure 7(b). It may be convenient to constrain anterior-posterior motion within limits by providing suitable stops, e.g. by means of an upstanding post 84 secured to the platform and an elongated hole 85 in the bearing pad 82. Thus, the pad 82 may move freely in an anterior-posterior direction into the post 84 abutting one of the ends of the elongated hole. An alternative method of providing stops is indicated in dotted lines in Figure 8(a) in which the recess in the plastics meniscus component 82 has a wall 86 against which the end face of the rail 83 abuts to limit the anterior-posterior movement in one direction.

Separate plastics pads 91, 92 (see Figures 9(a) and 9(b)) are an alternative arrangement supported on a common metal platform 93. Linear guidance is achieved by a metal rail 94, leaving a small clearance between

the pads and the rail. Again, the mating surface between the platform and the pads is curved. For two separate plastic components, both anterior-posterior translation and internal-external rotation are possible. For the latter, for bearing surfaces spaced apart 48 mm, only 0.8 mm inwards motion per side is needed to accommodate up to about ± 15 degrees of rotation.

Different ways can be envisaged to engage the plastic components, such as by T-shaped metal rails, under which a plastic lip is captured. This is illustrated in Figure 10, which is a view similar to Figure 7(c). A tibial bearing pad 101 is supported for sliding anterior-posterior motion on platform 103. The pad 101 is trapped and guided by rail 102 having a T-shaped profile section. Figure 10 also shows an alternative trapping and guidance means by lateral guides 104 having inwardly turned projections 105 which engage in slots in the plastics pad. A central guide rail is preferred since this is less prone to jamming.

In the construction described above the femoral components and tibial metal platform are made from a metal acceptable for use for implantation in the human body. Examples are cobalt-chromium and titanium alloys and stainless steels. The artificial patella (where present) and/or the plastics bearing components may be made from any biocompatible material capable of withstanding the imposed loads and providing appropriate bearing properties when in contact with a polished metal surface. Preferably, the plastics material should exhibit low friction properties under these conditions. Examples of suitable materials are ultra-high molecular weight polyethylene or acetal copolymers.

Claims

1. A tibial component of a knee prosthesis which comprises an upwardly concave metal platform (71,81) adapted to be secured to a resected tibia and a plastics bearing component (72,82) mounted for sliding movement thereon, characterised in that the mating surface between the plastics component and the metal platform is substantially cylindrical with the axis of the cylinder extending in a lateral-medial line.
2. A tibial component as claimed in claim 1 wherein the plastics bearing component comprises two plastics bearing components (91,92) supported on said metal platform, the mating surface between each plastics component and the metal platform lying on a cylinder whose axis extends in a lateral-medial direction.
3. A component as claimed in claim 2 wherein said plastics bearing components are located on opposite sides of a guide rail (94) extending in the anterior-posterior direction and serving to guide said plastics bearing components for sliding movement relative to the metal platform in an anterior-poste-

rior direction.

Patentansprüche

1. Tibialkomponente einer Knieprothese, umfassend eine nach oben konkave metallische Plattform (71, 81), dazu bestimmt, an einer resectierten Tibia befestigt zu werden, sowie eine Plastik-Lagerkomponente (72, 82), montiert zwecks gleitender Bewegung hierauf, dadurch gekennzeichnet, daß die zusammenpassende Fläche zwischen der Plastikkomponente und der metallischen Plattform im wesentlichen zylindrisch ist, wobei sich die Achse des Zylinders in einer seitlichen Mediallinie erstreckt.
2. Tibialkomponente nach Anspruch 1, wobei die Kunststoff-Lagerkomponente zwei Kunststoff-Lagerkomponenten (91, 92) umfaßt, die zwischen jeder Plastikkomponente und der metallischen Plattform auf einem Zylinder liegt, deren Achse sich in einer seitlich-medialen Richtung erstreckt.
3. Komponente nach Anspruch 2, wobei die genannten Kunststoff-Lagerkomponenten auf einander gegenüberliegenden Seiten einer Führungsschiene (94) angeordnet sind, die sich in der Vorwärts-Rückwärts-Richtung erstreckt und dazu dient die genannten Kunststoff-Lagerkomponenten bei einer Gleitbewegung relativ zur metallischen Plattform in Vorwärts-Rückwärts-Richtung zu führen.

Revendications

1. Composant tibial d'une prothèse pour le genou qui comprend une plate-forme métallique concave vers le haut (71, 81) adaptée pour être fixée à un tibia réséqué et un composant support en matière plastique (72, 82) montée pour un mouvement de glissement sur celle-ci, caractérisé en ce que la surface de raccordement entre le composant de matière plastique et la plate-forme métallique est sensiblement cylindrique, avec l'axe du cylindre s'étendant sur une ligne latéro-médiane.
2. Composant tibial selon la revendication 1, dans lequel la composant support en matière plastique comprend deux composants supports en matière plastique (91, 92) supportés sur ladite plate-forme métallique, la surface de raccordement entre chaque composant de matière plastique et la plate-forme métallique reposant sur un cylindre dont l'axe s'étend dans une direction latéro-médiane.
3. Composant selon la revendication 2, dans lequel lesdits composants supports en matière plastique sont situés sur les côtés opposés d'un rail guide (94) s'étendant dans la direction antéro-postérieure et servant à guider lesdits composants supports en

matière plastique pour un mouvement de glissement par rapport à la plate-forme métallique dans une direction antéro-postérieure.

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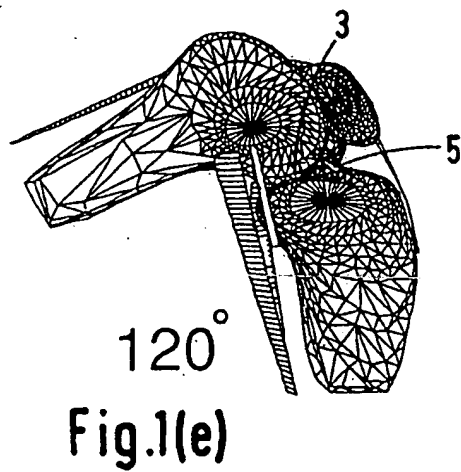
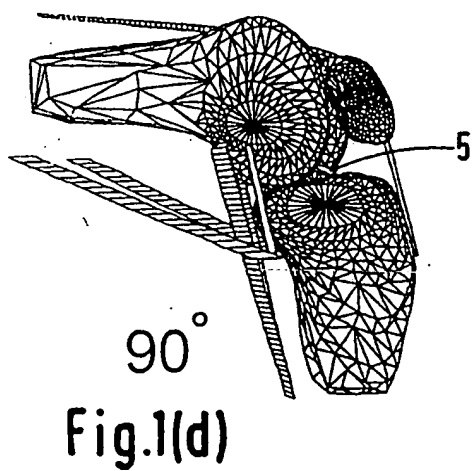
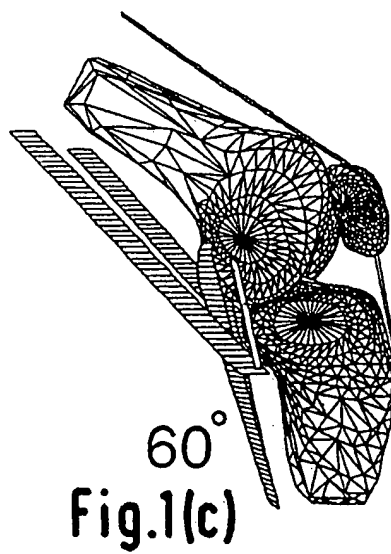
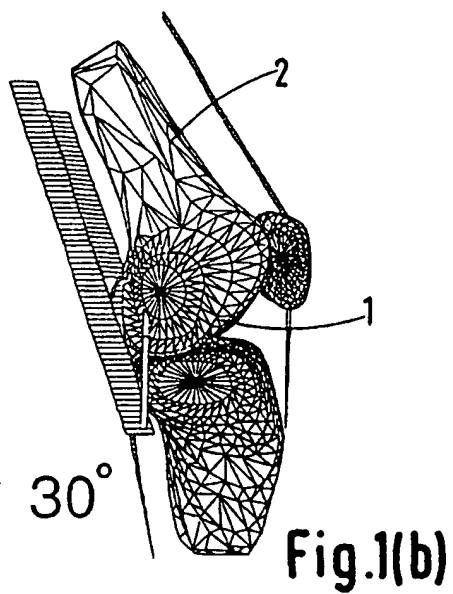
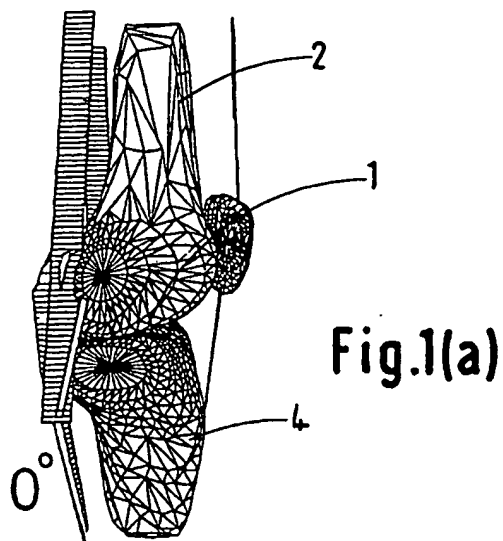
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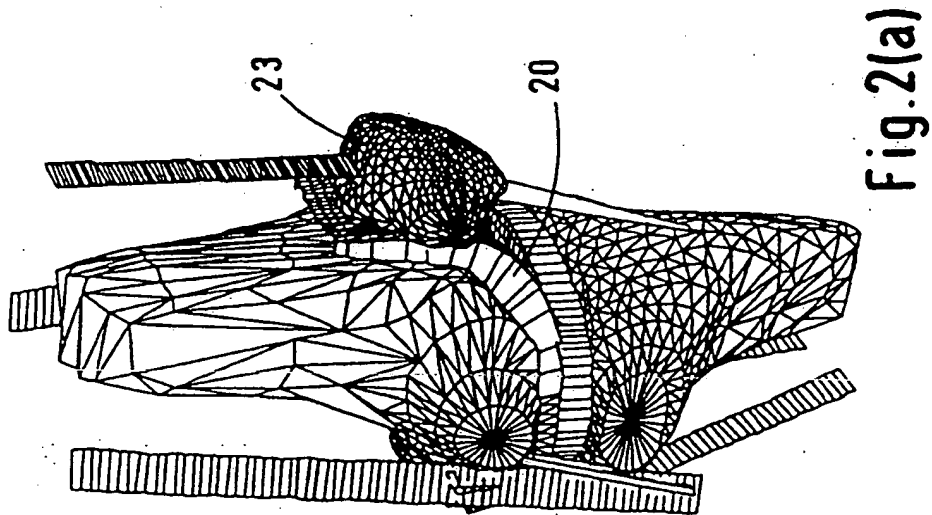
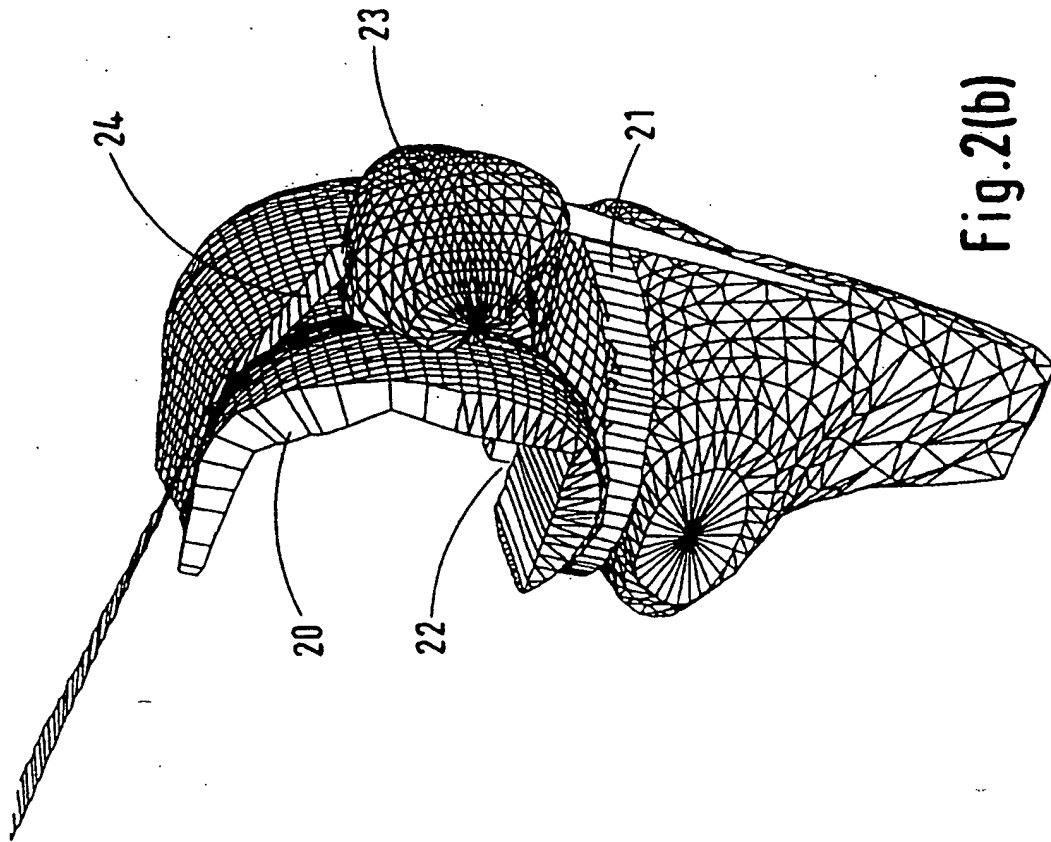
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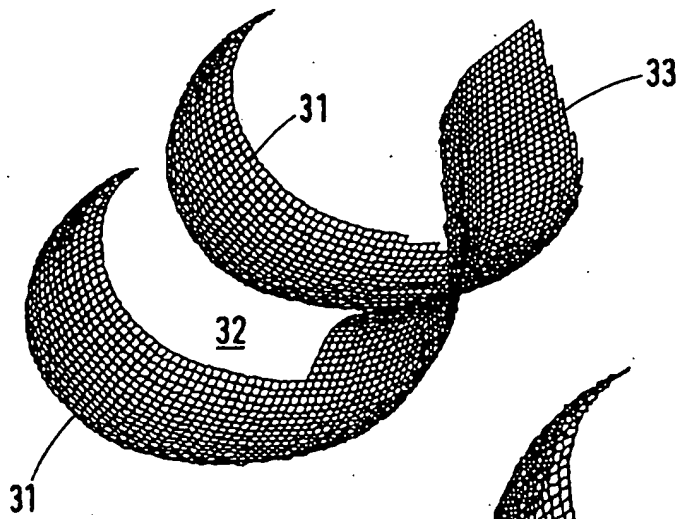


Fig. 3(a)

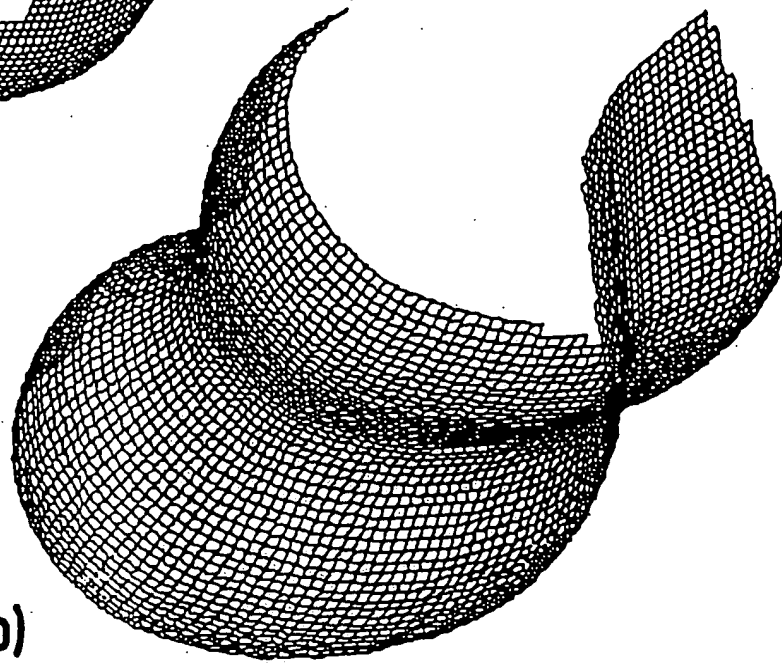


Fig. 3(b)

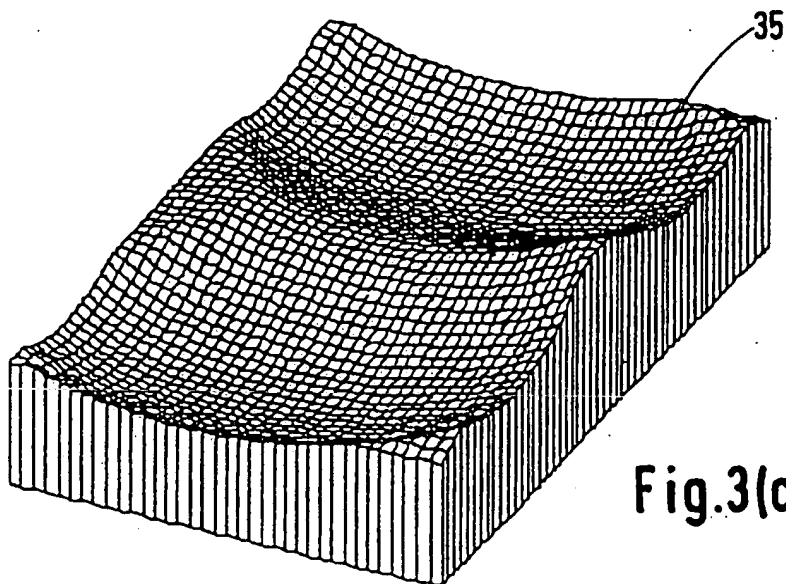
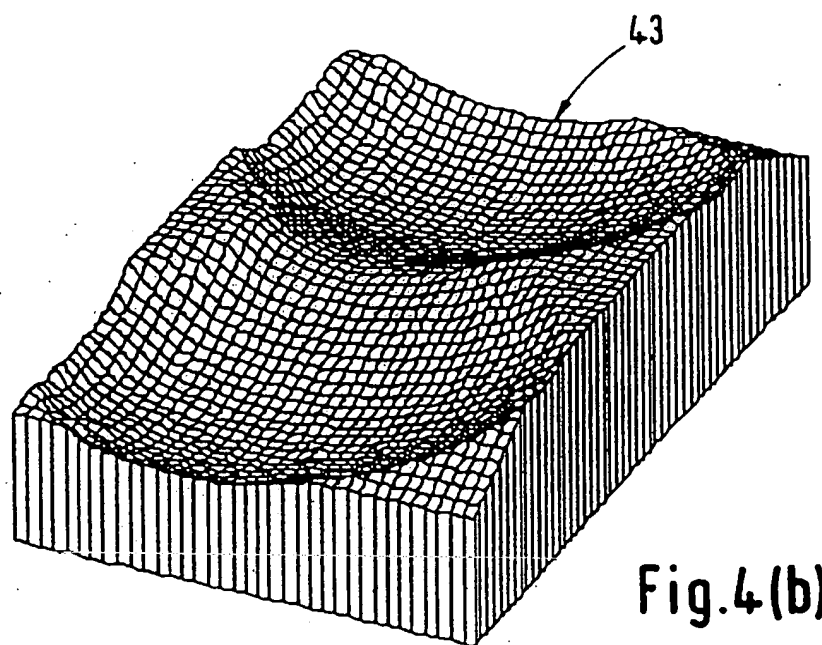
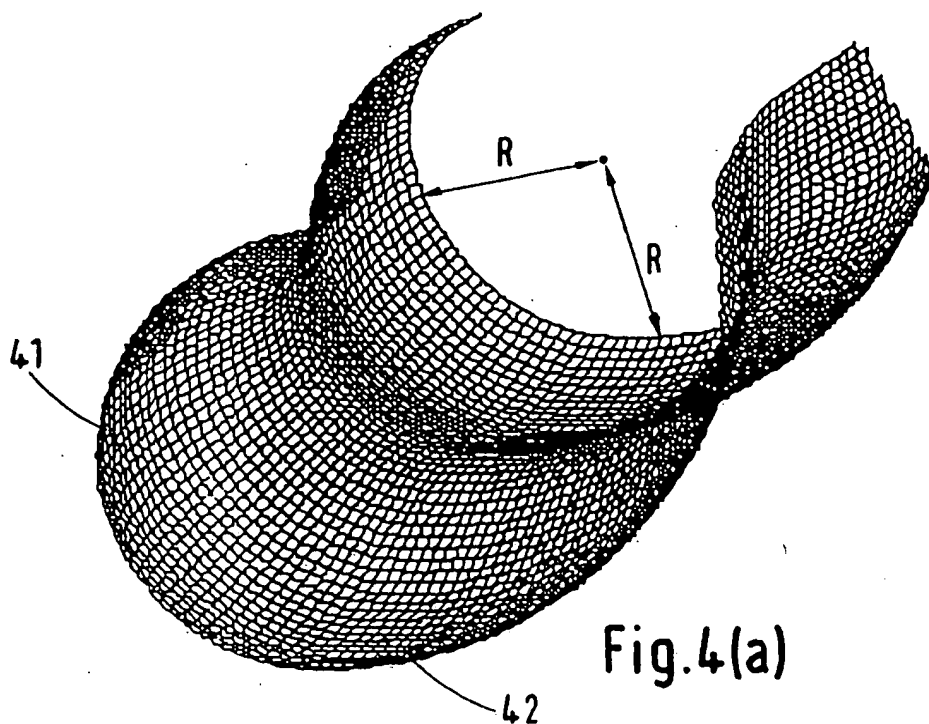


Fig. 3(c)



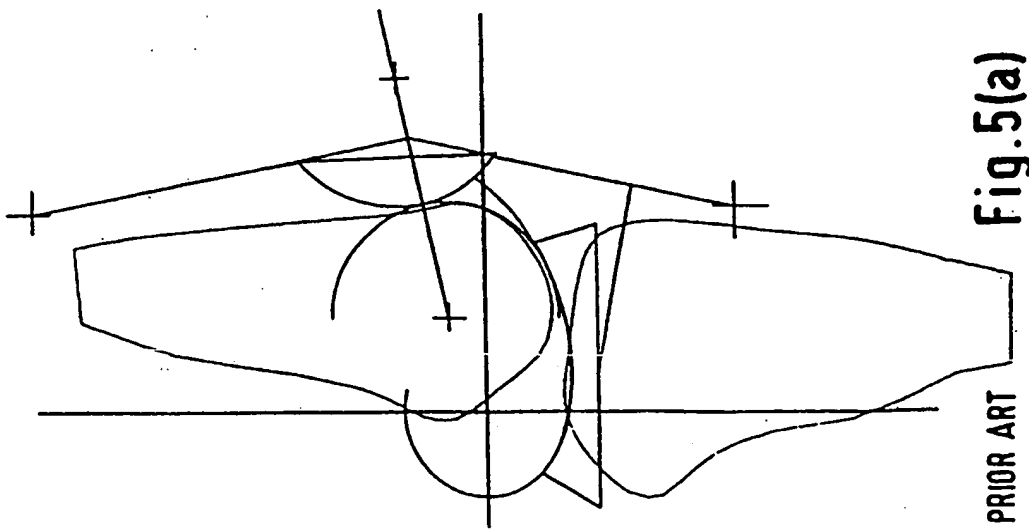


Fig. 5(a)

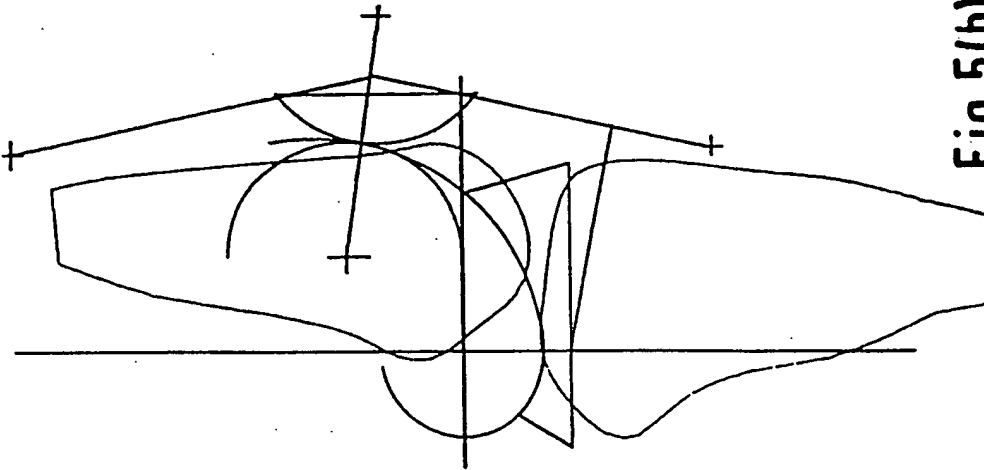


Fig. 5(b)

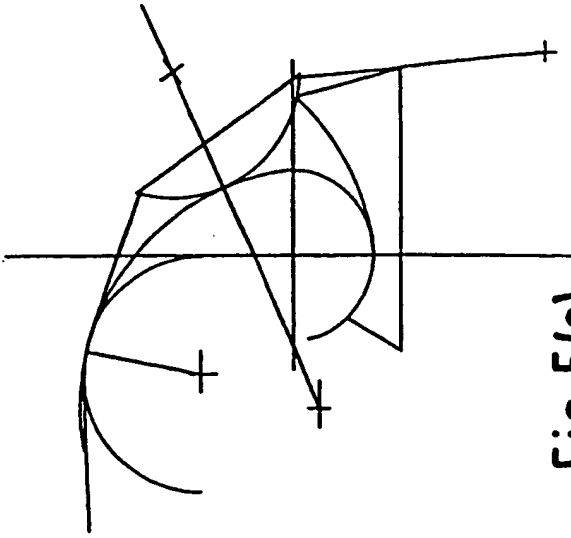


Fig. 5(c)

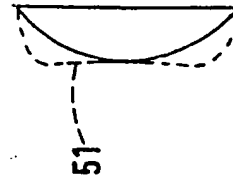
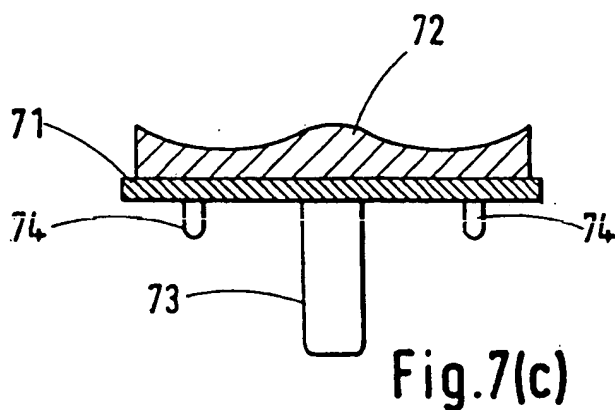
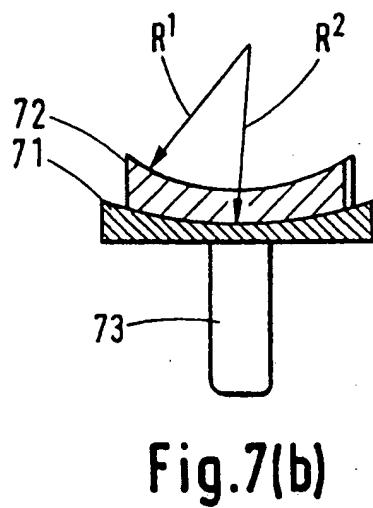
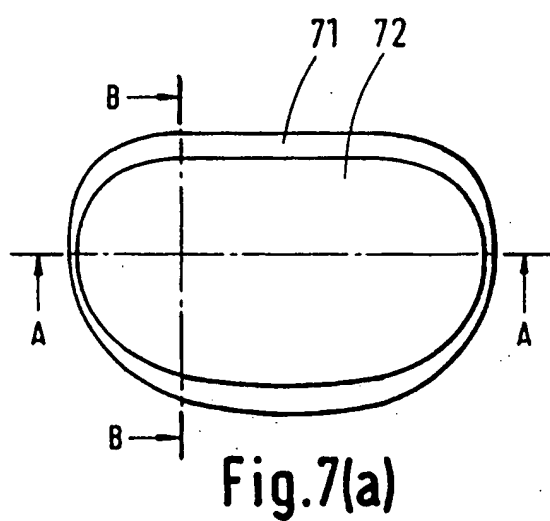
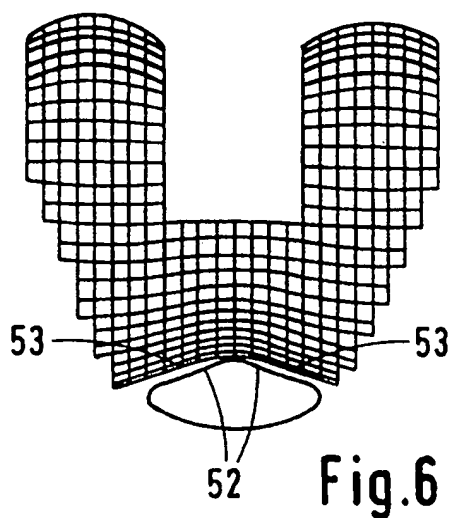


Fig. 5(d)



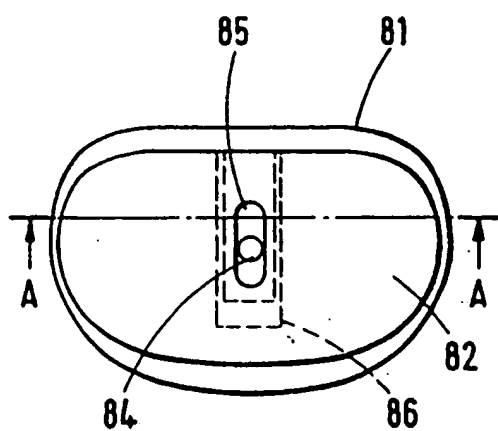


Fig. 8(a)

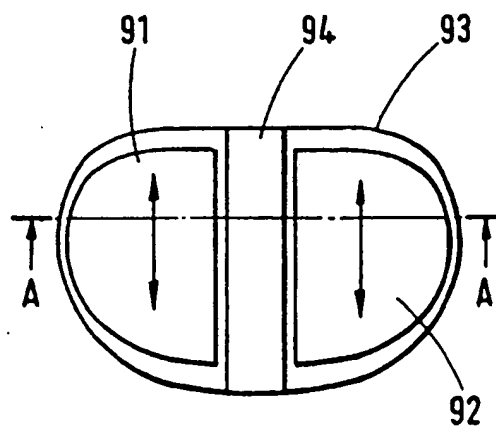


Fig. 9(a)

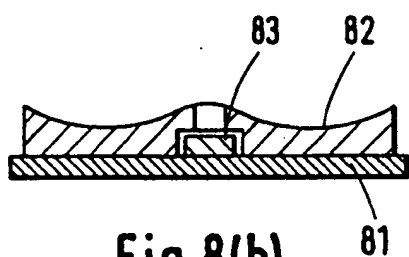


Fig. 8(b)

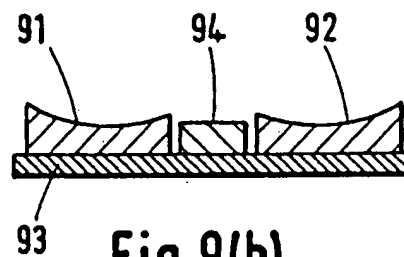


Fig. 9(b)

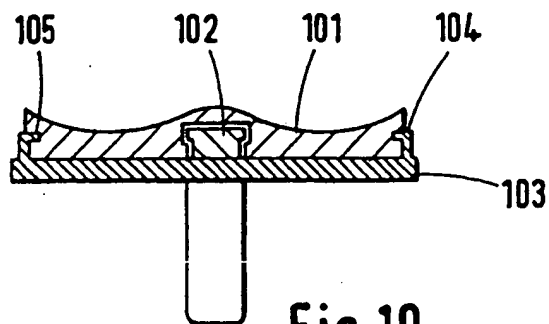


Fig. 10

Lisa M. Tittlemore

From: Lisa M. Tittlemore
Sent: Wednesday, June 15, 2005 10:28 AM
To: Kerry Timbers
Cc: 'Martin Siegel'; Joel Leeman
Subject: 6-15-05 to Greg Haight re Jim Southworth/expert witness (2815/502)

6-15-05 9:50 am

I spoke with Greg Haight at Haight Tramonte & Siciliano (<http://haighttramonte.com>) about his experience working with Jim Southworth. Greg has known Jim 6-7 years and currently Secure Pathways (Jim is President of Secure Pathways) is a client of Greg's.

Greg says that he has worked with Jim as an internal consulting expert but has never gone to trial with him; most of Greg's cases settle and he hasn't had to go to trial in a long time. Greg thinks Jim would be a good testifying witness. Greg would use Jim as a testifying expert witness if he had the need. Greg has seen Jim speak in meetings where the parties are in a dispute and Jim comes across as very well spoken, bright, someone who really knows his stuff. Jim is heavy-set guy and Greg thinks he is perceived as straightforward, knowledgeable w/o being arrogant, normal, reasonable guy. While Jim doesn't have the academic credentials, he has the knowledge and experience. Jim is well-respected by people in the telephony/computing field.

Greg has worked with Jim on litigation matters, but not patent cases (Greg handles business disputes regarding technology licensing etc., but doesn't do patent litigation himself).

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